A01183-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| Application No. | : | 10/074,744 |
| Applicant | : | Padidam |
| Filed | : | February 13, 2002 |
| Art Unit | : | 1636 |
| Examiner | : | Terry Alan McKelvey |
| Docket No. | : | A01183-US |
| Customer No. | : | 37978 |

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Reply to Restriction Requirement under 37 C.F.R. § 1.143**

Dear Sir:

In reply to the Restriction Requirement, mailed October 8, 2003, Applicants provisionally elect Group IV, claims 1-10 drawn to a method to reduce transcriptional interference using a spacer polynucleotide comprising SEQ ID NO: 4, with traverse. Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

## REMARKS

Claims 1-14 are pending in this application. The Examiner contends that this Application contains the following inventions or groups of inventions which allegedly are unrelated:

Group I, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 1;

Group II, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 2;

Group III, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 3;

Group IV, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 4; and

Group V, claims 11-14, drawn to cell and non-human organism.

The examiner suggested that the methods of Groups I-IV are drawn to the use of different nucleotide sequences which appear to be independent and distinct sequences and thus the methods that are drawn to the use of the independent and distinct sequences are independent and distinct.

In reply, and solely to be responsive to the Examiner's requirement, Applicants provisionally elect Group IV, claims 1-10, drawn to method to reduce transcriptional interference, using a spacer polynucleotide comprising SEQ ID NO: 4, with traverse.

Under 35 U.S.C. § 121, restriction may be required if "two or more independent and distinct inventions are claimed in one application." According to the interpretation provided in MPEP § 802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...." The term "distinct" is defined in MPEP § 801.02 as meaning that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or
3. Different field of search.

The above-cited language of 35 U.S.C. § 121 is clear in that the requirement to restrict an application to one of the inventions disclosed therein is proper only if the disclosed inventions are both independent and distinct. While Applicants take no position on the patentable distinctness of Groups I-V, Applicants submit that the claims of Groups I-V are not independent and are so linked as to form a single general inventive concept. The lengthy explanation provided in MPEP § 802.01 of why restriction can be properly required among independent or distinct inventions is in contradiction to the plain language of the statute and the related rules (37 C.F.R. § 1.142). Accordingly, a restriction based upon the alternative use of these terms is questionable.

However, even if one accepts the MPEP's interpretation of 35 U.S.C. § 121, the mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement.

According to the guidelines in MPEP § 803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

**Examination Of Claims 1-14 Does Not Present Undue Burden On The Examiner**

Applicants respectfully submit that prosecution of the claims of Groups I-V designated by the Examiner in the present Application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added). The groups designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application.

Accordingly, Groups I-IV are related to method to reduce transcriptional interference using 4 specific spacer nucleotides, all of which are classified in class 435, subclass 455, as indicated by the Examiner. In addition, according to MPEP 803.04, "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application." Further

MPEP 803.04 states "...up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Accordingly, the four sequences recited in claims 1-10 (Groups I-IV) should be examined by the Office without restriction.

Thus, all of these claims involve a fundamental determination of the novelty of a method to reduce transcriptional interference. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for a method to reduce transcriptional interference comprising SEQ ID NO: 1 of Group I would encompass the method to reduce transcriptional interference comprising SEQ ID NOs: 2, 3 or 4 of Groups II-IV, respectively. Performing an entire search covering the method to reduce transcriptional interference whether it is utilizing SEQ ID NO: 1, 2, 3 or 4 is less burdensome on the Examiner than separate searches, which necessarily involve duplication of searching efforts. Likewise with respect to Group V, performing the entire search covering the method to reduce transcriptional interference whether it is in a cell *in vitro* or in a cell *in vivo* is less burdensome on the Examiner than separate searches.

Thus, Applicants submit that the search and examination of the entire Application can be made without serious burden. Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction is believed to be in order.

## Conclusion

Applicants respectfully submit that claims 1-14 are drawn to a single general inventive concept as defined in 37 CFR § 1.1. Thus, the inventions of Groups I-V as hereinabove defined, are not unrelated, and the search of the claims of these groups does not impose an undue search burden on the Examiner.

Applicants submit respectfully that the Examiner has provided insufficient reasons in support of a restriction between the inventions of Groups I-V. In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the finding of lack of relatedness between the claims of Groups I-V. All of the claims should fairly be examined in a single application. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications directed to the subject matter of the non-elected claims of Groups I, II, III and V. If a telephone

interview would be of assistance in advancing prosecution of this application, Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

Respectfully submitted,

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Date: January 6, 2004

PTO/SB/17 (10-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# FEE TRANSMITTAL for FY 2004

*Effective 10/01/2003. Patent fees are subject to annual revision.*

☑ Applicant claims small entity status. See 37 CFR 1.27

| TOTAL AMOUNT OF PAYMENT | ($) 475.00 |
|---|---|

| *Complete If Known* | |
|---|---|
| Application Number | 10/074,744 |
| Filing Date | February 13, 2002 |
| First Named Inventor | Padidam |
| Examiner Name | TA McKelvey |
| Art Unit | 1636 |
| Attorney Docket No. | A01183-US |

## METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 502860

Deposit Account Name: RheoGene, Inc.

**The Director is authorized to:** *(check all that apply)*

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

SUBTOTAL (1) ($)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|
| Total Claims | | -20** = | | X | | = | |
| Independent Claims | | - 3** = | | X | | = | |
| Multiple Dependent | | | | | | = | |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet. | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for *ex parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | $475.00 |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 475.00

## SUBMITTED BY

(Complete *(if applicable)*)

| Name (Print/Type) | Camille Jolly-Tornetta | Registration No. (Attorney/Agent) | 48,592 | Telephone | 610/650-8734 |
|---|---|---|---|---|---|
| Signature | Camille Jolly-Tornetta | | | Date | January 6, 2004 |

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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